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paragraph discusses the ability of the overhang and corner flap of SIS to promote ingrowth, the language 'more rapid cell ingrowth' provides clear support that the SIS material itself (or another material with remodeling properties, e.g., additional extracellular collagen matrices other than SIS) is so processed to retain the ability to stimulate ingrowth of native tissue thereinto.

### Remarks

In the Office action of May 20, 2003, claims 1-6,10-13,15,16,19-22,25-30,36, and 46-55 are pending and should be in condition for allowance. The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.


Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner, if so necessary, to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

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## MARKED-UP CLAIMS

1 1. (Currently Amended) An implantable valve for a bodily passage of  
2 tubular shape, comprising:

3 a support frame configured for expansion to conform to a wall of  
4 the bodily passage, said support frame when expanded providing a plurality  
5 of side elements each defining a path extending at least partially  
6 longitudinally along the wall and at least partially circumferentially around  
7 the wall.

8 a plurality of leaflets, each leaflet thereof having a body  
9 extending from a wall-engaging outer edge to an inner edge proximate a  
10 corresponding inner edge of at least one ~~or another~~ other leaflet of the  
11 plurality of leaflets,

12 the inner edges of said plurality of leaflets cooperable to define  
13 an opening therebetween to permit fluid flow in a first direction along the  
14 bodily passage, and further cooperable to engage each other sufficiently to  
15 restrict ~~at least substantially occlude~~ fluid flow in a second direction  
16 opposing the first direction,

17 the outer edge of each one of the plurality of leaflets attached  
18 along one side element of said plurality of side elements and thereby  
19 adapted to engage a the wall of the bodily passage in said path extending  
20 oriented at least partially longitudinally therealong and at least partially  
21 circumferentially therearound such that the leaflet extends along said  
22 bodily passage away from the inner edges in said second direction;

1 2. (Original) The vascular valve of claim 1, wherein at least a portion of the  
2 body of the leaflet being flexible at least proximate the free edge thereof.

1 3. (Canceled)

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- 1 4. (Original) The implantable valve of claim 3 wherein the outer edges of  
2 the plurality of leaflets include overhanging material, the overhanging  
3 material extending beyond the frame to which the plurality of leaflets are  
4 attached.
- 1 5. (Currently Amended) The implantable valve of claim 3 wherein said  
2 frame comprises a wire to and around which the bodies of the leaflets are  
3 secured.
- 1 6. (Currently Amended) The implantable valve of claim 1 wherein the  
2 covering plurality of leaflets includes two leaflets such that when the frame  
3 is substantially flattened, it assumes a diamond shape with the inner edges  
4 of the two leaflets defining a slit therebetween.
- 1 7. (Original) The implantable valve of claim 3 wherein the body and the  
2 frame of each leaflet comprises an integral, one-piece member.
- 1 8. (Original) The implantable valve of claim 1 wherein said integral, one-  
2 piece member is molded into a generally flat shape.
- 1 9. (Original) The implantable valve of claim 7 wherein said integral, one-  
2 piece member is molded into a serpentine shape.
- 1 10. (Currently Amended) The implantable valve of claim 1 wherein the  
2 covering plurality of leaflets comprises an extracellular collagen matrix.
- 1 11. (Original) The implantable valve of claim 6 wherein the extracellular  
2 collagen matrix includes small intestinal submucosa.

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1 12. (Original) The implantable valve of claim 1 comprising two leaflets.

1 13. (Original) The implantable valve of claim 1 wherein the frame is  
2 adapted to assume a plurality of configurations, the plurality of  
3 configurations includes a generally flat configuration, whereby the frame in  
4 the generally flat configuration is generally diamond-shaped.

1 14. (Original) The implantable valve of claim 1 comprising at least three  
2 leaflets.

1 15. (Original) The implantable valve of claim 1 further including at least one  
2 barb to anchor the implantable valve to the wall of the bodily passage.

1 16. (Original) The implantable valve of Claim 15 wherein the at least one  
2 barb is integral projection extending from the frame.

1 17. (Original) The implantable valve of Claim 1 wherein the inner edge of  
2 at least one of the plurality of leaflets includes a flap, the flap configured to  
3 be extendable over the inner edge of adjacent one of the plurality of leaflets  
4 when the valve is in the closed condition.

1 18. (Original) The implantable valve of Claim 1 further including a  
2 circumferentially constraining mechanism that restricts radial expansion of  
3 the implantable valve in within the bodily passage.

1 19. (Currently Amended) An implantable valve for a bodily passage of  
2 tubular shape, comprising:

3 a frame that includes a plurality of legs, each of the legs  
4 originating from a pair of bends located about a first end of the implantable

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5 valve, and extending in an opposite direction therefrom, each of the plurality  
6 of legs terminating at the second end of the implantable valve such that the  
7 plurality of legs generally assume a serpentine configuration along the  
8 circumference of a bodily passage when situated therein,

9 a plurality of leaflets, each leaflet comprising a covering that  
10 includes one or more flexible materials, the leaflet including a body that  
11 comprises a wall-engaging outer edge and an inner edge, the outer edge at  
12 least partially attached to, and reinforced by one of the plurality of legs, the  
13 outer edge and the associated leg adapted to sealingly engage the inner  
14 wall of the bodily passage,

15 wherein the body of the leaflet extends inward from the wall of  
16 the bodily passage and extending toward the first end of the implantable  
17 valve where it terminates at the inner edge, the body and inner edge  
18 traversing the lumen of the bodily passage when situated therein and being  
19 configured such that the leaflet is cooperable with at least one other leaflet  
20 to define an opening that permits positive flow of fluid therethrough in a  
21 first direction, while the plurality of leaflets are further adapted to trap  
22 between the leaflets and the inner wall of the bodily passage fluid flowing  
23 in a second direction opposite the first direction and seal against one  
24 another to at least substantially reduce retrograde restrict fluid flow in said  
25 second direction.

1 20. (Original) The implantable valve of Claim 19 wherein the frame includes  
2 metal.

1 21. (Original) The implantable valve of Claim 20 wherein the frame  
2 comprises a superelastic alloy.

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1 22. (Original) The implantable valve of Claim 20 wherein the frame  
2 comprises a continuous wire structure.

1 23. (Original) The implantable valve of Claim 19 wherein the frame  
2 comprises a flattened structure, such as if formed from a sheet of metal.

1 24. (Original) The implantable valve of 19 wherein the frame includes at  
2 least one open section therealong, the at least one open section including  
3 a portion of the covering, the covering constraining the frame, thereby  
4 providing a bridge across the at least one open section.

1 25. (Original) The implantable valve of Claim 19 wherein the covering  
2 comprises a biomaterial.

1 26. (Original) The implantable valve of Claim 25 wherein the biomaterial  
2 includes an extracellular collagen matrix.

1 27. (Original) The implantable valve of Claim 26 wherein the extracellular  
2 collagen matrix comprises tissue derived from small intestinal submucosal  
3 tissue.

1 28. (Original) The implantable valve of Claim 19 wherein the frame  
2 comprises a polymeric material.

1 29. (Original) The implantable valve of claim 19 wherein the frame is  
2 adapted to assume a plurality of configurations, a first configuration of the  
3 plurality of configurations being a generally flat plane.

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1 30. (Original) The implantable valve of claim 19 wherein the covering  
2 includes two leaflets such that when the frame is in the generally flat  
3 configuration generally assumes a diamond shape with the inner edges of  
4 the two leaflets defining a slit therebetween.

1 31. (Original) The implantable valve of claim 30 wherein the frame  
2 generally assumes a rounded shape without well-defined corners when the  
3 frame is in the generally flat configuration, the covering comprising two  
4 leaflets.

1 32. (Original) The implantable valve of claim 19 wherein the frame includes  
2 at least three legs.

1 33. (Original) The implantable valve of claim 32 including three legs lying  
2 approximately 120° with respect to one another, the leaflets thereof so  
3 arranged such that the opening therethrough generally assumes a triangular  
4 shape when the frame is in the flat configuration prior to deployment.

1 34. (Original) The implantable valve of Claim 32 including four legs lying  
2 approximately 90° with respect to one another, the leaflets thereof so  
3 arranged such that the opening therethrough generally assumes a square  
4 shape when the frame is in the flat configuration prior to deployment.

1 35. (Original) The implantable valve of Claim 19 further including a  
2 circumferentially constraining mechanism attached about at least one valve  
3 leg, the circumferentially constraining mechanism configured to restricts  
4 radial expansion of the implantable valve in within the bodily passage.

1 36. (Currently Amended) An implantable vascular valve comprising:

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2 a covering including first and second oppositely facing curvilinear  
 3 surfaces when positioned across a vascular opening and also including at  
 4 least a first arcuate outer edge that exerts pressure against, and at least  
 5 forms a partial seal with, a vascular wall when positioned thereagainst; the  
 6 covering adapted to trap fluid in a curved structure defined by the arcuate  
 7 edge;

8 wherein the covering also includes an orifice extending through  
 9 the oppositely facing curvilinear surfaces;

10 wherein the covering traps fluid in said curved structure and the  
 11 orifice is in a closed position blocking fluid flow therethrough when fluid is  
 12 applied to the first oppositely curvilinear surface with the valve positioned  
 13 across the vascular opening; and

14 wherein the orifice is in an open position permitting fluid flow  
 15 therethrough when fluid is applied to the second oppositely curvilinear  
 16 surface with the valve positioned across the vascular opening.

1 37 - 41 (Canceled)

1 42. (Original) An implantable medical device comprising:

2 a covering including first and second oppositely facing curvilinear  
 3 surfaces when positioned across a vascular opening and also including at  
 4 least a resilient first arcuate outer edge that exerts pressure against, and  
 5 at least forms a partial seal with, a vascular wall when positioned  
 6 thereagainst;

7 wherein the covering is constrained in a predetermined direction,  
 8 whereby at least the pressure exerted against the vascular wall is  
 9 distributed substantially uniformly.

1 43. (Original) A multiple-sided intraluminal medical device comprising:



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2 a single frame having a closed circumference with an aperture  
 3 therethrough, said closed circumference having a plurality of sides, adjacent  
 4 ones of said plurality of sides and interconnecting bends, the frame adapted  
 5 to assume a plurality of configurations, a first configuration of the plurality  
 6 of configurations being in a generally flat plane;

7 wherein, the frame, having been formed in a first shape, is so  
 8 constrained into a second shape such that at least selected ones of the  
 9 plurality of bends, having been resiliently formed into a first angle between  
 10 respective adjacent ones of the plurality of sides, are maintained at a  
 11 second angle such that the frame is constrained against its bias to return  
 12 to the first shape such that the at least selected ones of the plurality of  
 13 bends would reassume the first angle between the adjacent ones of the  
 14 plurality of sides.

1 44. (Original) The device of claim 43 wherein the frame is constrained by  
 2 a flexible covering attached to the respective adjacent ones of the plurality  
 3 of sides.

1 45. (Original) The device of claim 43 wherein the frame includes a  
 2 continuous length of a resilient material that has been attached to itself  
 3 such that the at least selected ones of the plurality of bends are constrained  
 4 into the second angle.

1 46. (Currently Amended) An implantable valve for a bodily passage of  
 2 tubular shape, comprising:  
 3 a frame having a pair of legs, the frame being radially expandable  
 4 against the walls of the bodily passage wherein the legs define a path  
 5 extending at least partially longitudinally along the walls and at least  
 6 partially circumferentially around the walls,

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7 a plurality of leaflets comprising material derived from small  
 8 intestinal submucosa, each leaflet thereof having a body extending from a  
 9 wall-engaging outer edge to a free edge proximate a corresponding free  
 10 edge of at least one or another leaflet of the plurality of leaflets, the wall-  
 11 engaging outer edge of the leaflet being at least partially reinforced by one  
 12 of the plurality of legs of the frame,

13 the free edges of said plurality of leaflets cooperable to define an  
 14 opening therebetween to permit fluid flow in a first direction along said  
 15 bodily passage, and further cooperable to engage each other sufficiently to  
 16 ~~at least substantially occlude~~ restrict fluid flow in a second direction  
 17 opposing the first direction,

18 the outer edge of each said leaflet attached along one leg of the  
 19 pair of legs and thereby adapted to engage the walls of the bodily passage  
 20 oriented at least partially longitudinally the walls and at least partially  
 21 circumferentially ~~therearound the walls and~~ such that the leaflet extends  
 22 along said bodily passage away from the free edges in said second  
 23 direction,

24 at least a portion of the body of each said leaflet being flexible at  
 25 least proximate the free edge thereof, and

26 the plurality of leaflets having a first shape when unconstrained  
 27 and relaxed and being compressible into a second shape of smaller general  
 28 size for delivery to a treatment site in said bodily passage, and being  
 29 expandable at said treatment site upon delivery thereto for the outer edges  
 30 of said leaflets to sealingly engage the passage wall while the free edges  
 31 of the bodies of all said leaflets are moveable into and out of engagement  
 32 with each other in response to fluid flow.

1 47. (Currently Amended) An implantable valve for a bodily passage of  
 2 tubular shape, comprising:

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3 a self-expanding frame that includes a pair of legs, each of the  
 4 legs originating from a pair of bends located about a first end of the  
 5 implantable valve, and extending in a opposite direction therefrom, each of  
 6 the pair of legs terminating about the second end of the implantable valve  
 7 such that the pair of legs generally and collectively assume a serpentine  
 8 configuration along the circumference of a bodily passage when situated  
 9 therein;

10 a plurality of barbs, at least one barb attached to each of the pair  
 11 of legs, at least one of the barb including a terminal projection, the terminal  
 12 projection configured to releasably engage with a delivery system for  
 13 deployment of the implantable valve into the bodily passage;

14 a pair of leaflets, each leaflet comprising tissue derived from an  
 15 extracellular collagen matrix, each of the leaflets including a body that  
 16 comprises a wall-engaging outer edge and an inner edge, the outer edge at  
 17 least partially attached to, and reinforced by the frame, the outer edge and  
 18 the associated leg adapted to sealingly engage the inner wall of the bodily  
 19 passage,

20 wherein the body of the leaflet extends inward from the wall of  
 21 the bodily passage and extending toward the first end of the implantable  
 22 valve where it terminates at the inner edge, the body and inner edge  
 23 traversing the lumen of the bodily passage when situated therein and being  
 24 configured such that the leaflet is cooperable with the other of the plurality  
 25 of leaflets to define an opening that permits positive flow of fluid  
 26 therethrough, while the pair of leaflets are further adapted to trap fluid  
 27 between the leaflets and the inner wall of the vessel and seal against one  
 28 another to ~~at least substantially reduce~~ restrict retrograde flow.

1 27: 48. (Currently Amended) The implantable valve of claim 19 wherein  
 2 the frame is formed into the serpentine configuration.

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1 ~~28. 49.~~ (Currently Amended) The implantable valve of Claim 19 wherein  
2 the frame comprises a bioabsorbable material.

1 50. (Previously Added) An artificial valve prosthesis for placement within  
2 a bodily passage of a patient, the valve comprising:  
3 a plurality of leaflets comprising an inner edge and an outer edge;  
4 a supporting frame extending along the outer edge of each of the  
5 plurality of leaflets such that the outer edges thereof resiliently conform  
6 with the contours of the bodily passage when placed therein and exert a  
7 radial force thereagainst;

8 wherein the supporting frames extending along each leaflet of the  
9 plurality of leaflets are interconnected by a series of bends such that they  
10 collectively assume a generally serpentine configuration; and

11 wherein the inner edges of the plurality of leaflets traverse the  
12 vessel lumen such that the plurality of leaflets are cooperable to define an  
13 opening therebetween to permit fluid flow in a first direction along the  
14 bodily passage, while engaging each other sufficiently to restrict fluid flow  
15 in a second direction opposing the first direction.

1 51. (Previously Added) An artificial valve prosthesis for placement within  
2 a bodily passage of a patient, the valve comprising:

3 a plurality of legs each comprising a leaflet having an inner edge  
4 and an outer edge, and a support frame attached along the outer edge of  
5 the leaflet;

6 wherein the plurality of legs are interconnected such that the  
7 support frame includes a serpentine configuration in which the outer edges  
8 of the leaflets exert radial force against the walls of bodily passage and  
9 generally conform to the contours thereof; and

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10 wherein the inner edges of the plurality of leaflets traverse the  
11 vessel lumen such that the plurality of leaflets are cooperable to define an  
12 opening therebetween to permit fluid flow in a first direction along the  
13 bodily passage, while engaging each other sufficiently to restrict fluid flow  
14 in a second direction opposing the first direction.

1 52. (Previously Added) The implantable valve of claim 51, wherein the  
2 plurality of legs each include a first and second bend oriented in a first  
3 direction and at least one bend oriented in an opposite direction such that  
4 the leaflet and supporting frame thereof generally comprise a 'V' or 'U'  
5 shape.

1 53. (Previously Added) The implantable valve of claim 51, wherein the  
2 plurality of legs comprise three legs oriented approximately 120° apart with  
3 respect to one another.

1 54. (Previously Added) The implantable valve of claim 51, wherein the  
2 plurality of legs comprise four legs oriented approximately 90° apart with  
3 respect to one another.

1 55. (Previously Added) An implantable valve for a bodily passage of tubular  
2 shape, comprising:

3 a support frame configured for expansion to conform to a wall of  
4 the bodily passage, said support frame when expanded providing a plurality  
5 of side elements each defining a path extending at least partially  
6 longitudinally along the wall and at least partially circumferentially around  
7 the wall,

8 a plurality of leaflets comprising an extracellular collagen matrix  
9 material, each leaflet thereof having a body extending from a wall-engaging

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10 outer edge to an inner edge proximate a corresponding inner edge of at  
11 least one other leaflet of the plurality of leaflets,  
12 the inner edges of said plurality of leaflets cooperable to define  
13 an opening therebetween to permit fluid flow in a first direction along the  
14 bodily passage, and further cooperable to engage each other sufficiently to  
15 restrict fluid flow in a second direction opposing the first direction,  
16 the outer edge of each one of the plurality of leaflets attached  
17 along one side element of said plurality of side elements and thereby  
18 adapted to directly engage the wall of the bodily passage therearound and  
19 provide ingrowth of adjacent native tissue into the extracellular collagen  
20 matrix material.

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